REMARKS

Claims 1 – 4, 8 and 17 - 20 are pending. No claims are hereby added. Claim 8 is cancelled. Claim 1 is amended to include the limitations of claim 8 and thus corresponds to claim 8 as previously presented. All claims were rejected under 35 U.S.C. 103 as being obvious over Dutcher (US 4,381,013) in view of Evans, III, et al. (US 4,854,330). This rejection is respectfully traversed.

The claims require a stylet having a straight proximal segment, a curved intermediate segment extending from the proximal segment and a straight distal segment extending from the curved segment. All three segments are clearly visible in Dutcher. The straight proximal and distal segments are plainly visible in the inserted drawing. The area intermediate the straight segments is curved, as required by the claims.

The claims further require a taper beginning in the intermediate, curved segment. In the Dutcher stylet is present only in the straight distal portion of the stylet, directly contrary to the requirements of the claims. This much, apparently, is no longer in dispute.

The new ground of rejection is based upon the following argument:

> in diameter". It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the j-shaped stylet of Dutcher with a taper zone extending within the curved intermediate segment as disclosed by Evans, III et al. in order to provide the predictable results of enhancing the maneuverability while navigating the vasculature to facilitate implantation of the medical lead.

In order for the rejection to be proper under the recently issued Patent Office Guidelines for Section 103 rejections, the above argument would have to be factually correct and would have to conform to common sense and be set forth with sufficient specificity to demonstrate that it does so. See the Perfect Web Technologies v.

InfoUSA opinion, cited in the new guidelines. It is respectfully asserted that the above argument fails on all counts.

First, the rejection is not set forth with specificity. The Dutcher stylet has two components, including an inner component and the outer component. In previous rejections, the tapered portion was identified as being part of the outer, coiled portion of the stylet, ending in the tapered screwdriver tip, i.e. the rotatable portion.

Correspondingly, Applicant's first guess was that the examiner was proposing to extend the tapered portion of Dutcher (the screwdriver tip) along a curve. However, as a screwdriver tip with a pre-formed curve would be non-functional, Applicants assume this interpretation is incorrect. This issue was discussed in the previously filed Appeal Brief and should be familiar to the Examiner.

Applicant's second guess was that the thus assume that the Examiner's argument was that the proposed change to Dutcher was to taper the coiled portion of the rotatable outer component of the Dutcher stylet. However, this portion of the stylet is not formed with a curve and indeed if it had a pre-formed curve, it would similarly fail as a screwdriver, as the end would tend to whip around when rotated. This is the same issue as discussed above.

Applicant's third guess was that the Examiner's proposal was to taper the end of the pre-curved inner portion of the Dutcher stlylet. This proposal at least does not render the screwdriver function of Dutcher stylet non-functional. However, it is respectfully asserted to nonetheless be contrary to the teaching of Dutcher.

The purpose of the preformed curve in Dutcher is to hold the distal tip of the lead stationary while the screwdriver tip on the outer component of the lead is rotated. To the extent the inner portion of the Dutcher stylet would be tapered over the curved portion, it would correspondingly have a reduced ability to hold the lead tip stationary during this procedure.

In use, the majority of the Dutcher stylet is located in the lead body along its length as it extends through the vasculature (typically the subclavian or cephalic vein)

and into the heart. The configuration of the lead body along this length is substantially constrained to the shape of the vasculature. In use, the distal end of the lead is located within the atrium, where the configuration of the lead body is unconstrained by the vasculature. It is for this reason that the distal end of the inner component of the Duthcher stylet is pre-formed into a curved configuration. As such, the distal, curved portion of the inner component is the portion of the stylet that has to most reliably hold its curved configuration in use. It correspondingly needs to be the least flexible portion of the stylet, not the most flexible. Tapering it would thus directly interfere with its functionality. This is the portion of the Dutcher lead that is least likely to benefit from being tapered. As such, the argument for obviousness defies common sense.

The Evans III stylet, is provided with a taper in its curved portion for a different purpose, The curved portion of Evans III is intended to have its primary function in areas of the vasculature in which the catheter is constrained by the surrounding vasculature. The taper is intended to make it the most flexible portion and has its primary effect while the catheter is constrained by the walls of the vessels though which it passes. This is precisely the opposite circumstance from that in which the curved portion of the Dutcher stylet is intended to have its primary effect and directly contrary to the intended purpose of the Dutcher stylet.

In making an argument for the obviousness of a modification to a pre-existing device, proposed change has to make sense in the context of the pre-existing device. The Examiner's change does not meet this requirement.

The world is full of tapered, flexible structures, and the purpose of the taper is generally, as in Evans III, to make the device more flexible. The curved portion of the inner component of the Dutcher stylet is the portion that needs to be least flexible. No matter where the Examiner finds a tapered structure, it seems unlikely that the purpose of that taper would be consistent with the purpose of the pre-formed curve of the inner portion of the Dutcher stylet.

The Examiner is correct that adding a taper to Dutcher would make it more flexible. However, it would also reduce its usefullness. Not all structures are made

more useful by being made more flexible. The curved portion if the Dutcher stylet is one of them.

The rejection of over Dutcher and Evans III is respectfully asserted to be deficient because it is not set forth with sufficient clarity. More importantly, it is respectfully asserted to be deficient as contrary to common sense. withdrawal of the rejection of all claims is respectfully requested.

With allowance of claims 1 and 17, the withdrawn claims dependent thereon should also be allowed. Allowance of withdrawn claims 9 – 16 and 24 – 30 is therefore also respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

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